

**REMARKS/ARGUMENTS**

By the present Amendment, claims 1-7, 10, 31-33, 35, 36, 39, 40, 42-45, 47, 50-52, 55-68, 85-87, 112-119, and 152-156 are pending in this application. Claims 8, 19, and 157 have been withdrawn. Claims 34, 38, 120, and 121 are canceled herein without prejudice or disclaimer. Applicants reserve the right to file one or more continuation, continuation-in-part, and/or divisional applications directed towards any canceled subject matter. Claims 1, 31, and 112 are amended herein. Basis for these amendments may be found throughout the specification and claims as originally filed. No new matter has been added.

**35 USC § 112, first paragraph**

The Action has rejected claims 1-7, 10, 31-36, 38-40, 42-45, 47, 50-52, 55-68, 85-87, 112-121, and 152-156 under 35 USC §112, first paragraph, as allegedly failing to comply with the enablement requirement. The basis for this rejection is that the specification provides enablement for methods of treatment of a subject with cancer comprising administering a composition comprising a pattern recognition receptor ligand and a delivery vehicle comprising a liposome, where the liposome is a positively charged liposome, however, it allegedly does not reasonably provide enablement for methods comprising the administration of a composition comprising a pattern recognition receptor ligand and a delivery vehicle comprising a liposome, where the liposome is a neutral liposome or a negatively charged liposome. Applicants respectfully disagree.

For business reasons and in an effort to advance prosecution of the pending application towards grant of a patent, the claims are amended herein to encompass methods comprising administering a composition comprising a pattern recognition ligand and a delivery vehicle, wherein the liposome is a positively charged liposome, which renders this rejection moot. Applicants respectfully request reconsideration and removal of this rejection.

**35 USC § 103**

**Dow (US 6,693,086) in view of Milas**

The Action has affirmed the rejection of claims 1-7, 10, 31-36, 39, 40, 42-44, 61, 64, 65, 85-87, 112, 118, 120, 151, and 156 under 35 USC § 103(a) as allegedly being obvious over Dow (US 6,693,086) in view of Milas.

The Action alleges that the declaration submitted on November 16, 2007 under 37 CFR § 1.132 is allegedly insufficient to overcome this rejection based on the fact that Dow is a reference available under 35 USC § 102(e) because it is a patent to another. In particular, the Action asserts that the statements provided in the declaration allegedly do not establish that the invention disclosed but not claimed in the '086 patent was derived by the inventor of this application because the inventor of this application is the inventive entity of Stephen W. Dow and Jeffrey Fairman.

According to the MPEP 2136.05, a 35 USC § 102(e) rejection can be overcome by showing that the reference is describing applicant's own work. *In re Matthews*, 408 F.2d 1393, 161 USPQD 276 (CCPA 1969). "The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art." *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816 (Fed. Cir. 1988). The issue turns on what the evidence of record shows as to who invented the subject matter. *In re Whittle*, 454 F.2d 1193, 1195, 172 USPQ 535, 537 (CCPA 1972). In fact, even if applicant's work was publicly disclosed prior to his or her application, applicant's own work may not be used against him or her unless there is a time bar under 35 USC § 102(b). *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)).

In *re DeBaun*, the court reversed an examiner's obviousness rejection over a patent to named inventors DeBaun and Noll that issued less than one year before the filing date of the pending application. DeBaun, the sole inventor identified on the pending application, argued that the art cited against him was not prior art under 35 USC § 102(e), and submitted a declaration that he was the sole inventor of the subject matter on which the examiner's rejection relied. As the court put it: "What is significant is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art, and the subject matter

of the claims in question, represent the work of a common inventive entity." *Riverwood International Corporation v. R.A. Jones & Co., Inc.*, 324 F.3d 1346 citing *In re Debaun*, 687 F.2d 459, 462 (CCPA 1966).

In the present case, applicants have submitted a new declaration under 37 CFR § 1.132, in which the common inventive entity of the subject matter relied upon in the '086 patent and the subject matter of the rejected claims in the pending application is Stephen W. Dow. In this declaration, Dow has declared that he is the inventor of the subject matter of the '086 patent relied upon by the Action, i.e. claims 34-37 and column 6, lines 41-58; column 3, lines 8-25; column 13, lines 14-29; and column 13, lines 34-35; and that he is the inventor of the subject matter of the claims in question, i.e. claims 1-7, 10, 31-36, 39, 40, 42-44, 61, 64, 65, 85-87, 112, 118, 120, and 156. (Note: claim 151 was previously canceled in our Amendment of November 16, 2007). Thus, although the listed inventors of the present application include Stephen W. Dow and Jeffrey Fairman, the inventor of the subject matter of the claims in question is Stephen W. Dow. (Stephen W. Dow and Jeffrey Fairman continue to be co-inventors of pending claims 45, 47, 50-52, 55-60, 62, 63, 66-68, 113-117, 119, and 152-155). Therefore, the '086 patent to Dow is not available as a reference under 35 USC § 102(e) because it is not a patent to another. Applicants respectfully request reconsideration and removal of this rejection.

#### **Raz (US 6,534,062) in view of Whitmore or Dow**

The Action has rejected claims 1-7, 10, 31-36, 39, 40, 42-45, 52, 61, 64, 65, 85-87, 112, 113, 118-120, 151, and 156 under 35 USC § 103(a) as allegedly being obvious over Raz (US 6,534,062) in view of Whitmore, M. et al (Gene Therapy, 6:1867-1875, 1999) or Dow, S.W. et al. (The Journal of Immunology, 163:1552-1561, 1999). Applicants respectfully disagree.

As amended herein, the invention as defined by the claims, distinguishes over the cited references by claiming methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome.

Raz does not teach or suggest any such methods. Instead, this reference teaches methods for T helper-independent activation of an antigen-specific cytotoxic T lymphocyte (CTL) by administering an immunostimulatory nucleic acid molecule in an amount effective to increase

an antigen-specific CTL response. This reference broadly teaches immunostimulatory nucleic acids and formulations for their delivery. This reference, however, does not teach or suggest any methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims. Absent a teaching or suggestion in the cited reference, one of skill in the art would not have been motivated to do what applicants now claim. Nor would one of skill in the art have any reasonable expectation of success in arriving at the claimed invention based on the teachings of this reference. Raz teaches methods for T helper-independent activation of an antigen-specific CTL by administering an immunostimulatory nucleic acid molecule in an amount effective to increase an antigen-specific CTL response. One of skill in the art, based on these teachings or on the knowledge generally available to them, would have no reasonable expectation of successfully arriving at methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the claimed invention.

Nor do the teachings of Whitmore or Dow cure the defects of Raz. Instead, Whitmore teaches nonviral gene delivery using cationic liposome-based plasmid DNA complexes (e.g. a lipopolyplex consisting of DOTAP:cholesterol liposomes, protamine sulfate, and plasmid DNA (LPD) for systemic gene delivery in pulmonary metastasis); whereas Dow teaches cationic-lipid DNA complexes for inducing systemic immune activation and antitumor activity. These references, however, do not teach or suggest any methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims. Absent a teaching or suggestion in the cited references, one of skill in the art would not have been motivated to combine the teachings of Raz with either Whitmore or Dow in order to do what applicants now claim. Nor would one of skill in the art, either based on the teachings of these references or on the knowledge generally available to them, have any reasonable expectation of success in arriving at methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims.

Therefore, the claimed invention is not obvious over the teachings of Raz in view of Whitmore or Dow. Applicants respectfully request reconsideration and removal of this rejection.

**Raz (US 6,534,062) in view of Whitmore or Dow in view of Maes**

The Action has rejected claims 1, 31, 61, and 62 under 35 USC § 103(a) as allegedly being obvious over Raz (US 6,534,062) in view of Whitmore, M. et al (Gene Therapy, 6:1867-1875, 1999) or Dow, S.W. et al. (The Journal of Immunology, 163:1552-1561, 1999) in view of Maes (US 3,725,545). Applicants respectfully disagree.

As amended herein, the invention as defined by the claims, distinguishes over the cited references by claiming methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome.

As discussed above, Raz in view of Whitmore or Dow does not teach or suggest the claimed invention. Maes does not cure the defects of these references because this reference does not teach or suggest any methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims. Instead, this reference teaches reacting single-stranded or multi-stranded nucleic acid polymers with cationically charged polymers, which produces complex substances capable of enhancing the production of antibodies when introduced in conjunction with an antigen into an animal host. These references, either alone or in combination, do not teach or suggest any methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims. Absent a teaching or suggestion in the cited references, one of skill in the art would not have been motivated to combine the teachings of Raz with Whitmore or Dow and Maes in order to do what applicants now claim. Nor would one of skill in the art, either based on the teachings of these references or on the knowledge generally available to them, have any reasonable expectation of success in arriving at methods for treating cancer by administering a ligand for a pattern recognition receptor and a delivery vehicle comprising a positively charged liposome as required by the instant claims. Therefore, the claimed invention is not obvious over

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the teachings of Raz in view of Whitmore or Dow and in view of Maes. Applicants respectfully request reconsideration and removal of this rejection.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



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